

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	
LITIGATION)	MDL No. 1456
_____)	
)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:)	
)	
<i>United States of America, ex rel. Ven-a-Care</i>)	Subcategory Docket: 06-CV-11337-
<i>of the Florida Keys, Inc. v. Abbott</i>)	PBS
<i>Laboratories, Inc.,</i>)	
CIVIL ACTION NO. 06-CV-11337-PBS)	Hon. Patti B. Saris
)	
<i>United States of America ex rel. Ven-a-Care of</i>)	
<i>the Florida Keys, Inc. v. Dey, Inc., et al.,</i>)	
CIVIL ACTION NO. 05-11084-PBS)	
)	
<i>United States of America ex rel. Ven-a-Care of</i>)	
<i>the Florida Keys, Inc., et al. v. Boehringer</i>)	
<i>Ingelheim Corporation, Inc., et al., CIVIL</i>)	
ACTION NO. 07-10248-PBS)	

**UNITED STATES' COMMON MEMORANDUM OF LAW IN OPPOSITION TO THE
DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT PERTAINING TO THE
STATUTE OF LIMITATIONS AND DEFENDANTS' MOTIONS TO DISMISS**

All three defendants argue that relator should be dismissed from this action based on the public disclosure and original source provisions found in the False Claims Act (FCA), 31 U.S.C. § 3730(e)(4), and that summary judgment should be granted in their favor on pre-intervention claims.¹ The argument fails. As set forth below, even if the relator's complaint were dismissed on such grounds, it would have no effect on the United States' claims in this action, because the claims may validly relate back to a relator complaint that is subsequently found to be jurisdictionally defective. Moreover, to the extent defendants rely upon government reports as

¹On July 13, 2009, the Court granted the parties' joint motion for a briefing schedule (Master Docket ("MD") #6252), which provided that plaintiffs would separately respond to defendants' arguments on this issue.

public disclosures, this Court has already ruled that although such reports “do disclose” some of the “essential background information” in relator’s complaint, “they do not reveal nearly enough information” to qualify as public disclosures under the FCA. *United States ex rel. Ven-A-Care of the Fla. Keys v. Actavis Mid Atlantic LLC*, 2009 WL 3171798 at *3 (D. Mass. Oct. 2, 2009).

ARGUMENT

I. The Government’s Claims Against the Defendants Relate Back to the Claims in the Relator’s Original Complaint Even if Relator Were Barred By the FCA’s Public Disclosure Provisions.

Defendants’ argument that because relator’s complaint is barred by the public disclosure provisions of the FCA, 31 U.S.C. § 3730(e)(4), the United States’ complaints-in-intervention cannot relate back to the relator’s complaint, Abbott Memorandum of Law, MD #6186 at 39; Dey Memorandum of Law, MD #6194 at 39; Roxane Memorandum of Law, MD #6200 at 34, is directly contrary to the Supreme Court’s ruling in *Rockwell Int’l Corp. v. United States*, 549 U.S. 457, 478 (2007), and the First Circuit’s decision in *Connectu v. Zuckerberg*, 522 F.3d 82 (1st Cir. 2008). It is also inconsistent with recent amendments to the FCA that specifically address the government’s ability to relate back to relator’s original complaint.

In *Rockwell*, the Supreme Court held that where the United States has intervened, the only effect of a finding that a relator is barred by the public disclosure provisions of the FCA is that the relator is eliminated from the action. The Court retains jurisdiction over the action as one brought by the Attorney General. Further, as evidenced by the Supreme Court and later the Tenth Circuit in *Rockwell* following remand, the government’s complaint does continue to relate back to the original *qui tam* complaint that commenced the action regardless of whether the relator is barred by the public disclosure provisions of the FCA.

In *Rockwell*, the Supreme Court analyzed the effect of a relator being disqualified by the public disclosure bar in a *qui tam* action in which the government had intervened several years after the filing of the original complaint and obtained a judgment against defendant. The relator in *Rockwell* brought his *qui tam* complaint in July 1989. 549 U.S. at 463. The government did not intervene until November 1996, at which time it added the specific allegations (involving “pondcrete”) which defendant claimed had been publicly disclosed. *Id.* at 464-65. The false pondcrete claims were submitted by defendant Rockwell between April 1987 and September 1988. *Id.* at 466. Turning to the issue of the Court’s jurisdiction over the government’s complaint in intervention, the Supreme Court considered whether a court’s ruling that a relator is not an original source “cast into doubt” the court’s jurisdiction over the government’s claims, recognizing that “§ 3730(e)(4)(A) bars jurisdiction over any action brought under § 3730 . . . unless the action is brought (1) by the Attorney General or (2) by an original source; and we have concluded that this is brought by neither.” *Id.* at 478. Nonetheless, the Supreme Court concluded:

Not even petitioners have suggested the bizarre result that the Government’s judgment must be set aside. It is readily enough avoided, as common sense suggests it must be, by holding that an action originally brought by a private person, which the Attorney General has joined, *becomes an action brought by the Attorney General once the private person has been determined to lack the jurisdictional prerequisites for suit.* . . . What is cured here, by the jurisdictional ruling regarding Stone’s claim, is the characterization of the action as one brought by an original source. The elimination of Stone leaves in place an action pursued only by the Attorney General, that can reasonably be regarded as being “brought” by him for purposes of § 3730(e)(4)(A).

Id. (emphasis added).²

²The court likened the result to what occurs in “diversity-jurisdiction cases, where the ‘courts of appeals ... have the authority to cure a jurisdictional defect by dismissing a dispensable nondiverse party.’” *Id.* Citations omitted.

Contrary to defendants' contention here, the action "brought by the Attorney General" in such a circumstance is not limited – for statute of limitations purposes – to the specific Complaint filed by the Attorney General upon intervention. Instead, the relator's original complaint is now treated as if filed by the United States, with the United States' complaint-in-intervention relating back to the original complaint.³

Although the Supreme Court did not address the statute of limitations directly, the facts of the *Rockwell* decision support this result. Under defendants' argument, the government in *Rockwell* would have been limited to claims arising after November 1990 – six years prior to the government's intervention. The Court left the government's pre-November 1990 claims untouched. After the Supreme Court ruled, the Tenth Circuit then entered an order affirming the judgment in favor of the United States and vacating the part of the judgment entered in favor of the relator. *United States ex rel. Stone v. Rockwell Int'l Corp.*, 492 F. 3d 1157 (10th Cir. 2007). It is clear that the Supreme Court and the Tenth Circuit both concluded, *sub silencio*, that the government's pondcrete allegations related back to the relator's original complaint.

This result is also consistent with the First Circuit's interpretation of the *Rockwell* decision in the *Connectu* decision. The defendants in *Connectu* argued that because the plaintiff's original complaint improperly relied on diversity jurisdiction as the basis for suit in federal court, the plaintiffs' amended complaint, which properly asserted federal question jurisdiction, could not relate back to the original complaint. Relying on *Rockwell*, the First

³Defendants cite language from this Court's ruling on Dey's motion to dismiss, where the Court noted, "[i]f the Court did not have jurisdiction over Ven-A-Care's first pleading, the government's complaint-in-intervention cannot properly relate back." 498 F. Supp. 2d 389, 399-400 (D. Mass. 2007). It is not clear whether the Court is merely summarizing Dey's position, or actually speaking for itself. However, even if the latter, this Court's dicta in the Dey motion to dismiss ruling does not address the jurisdictional effect of a finding that the relator is barred by the FCA's public disclosure provisions.

Circuit held that the jurisdictional inquiry should focus on the amended complaint. *Connectu*, 522 F.3d at 91. Specifically addressing the defendants’ argument that relation back was improper because the district court lacked jurisdiction over the original complaint, the First Circuit wrote, “the argument mixes plums with pomegranates. Rule 15(c)’s language about the relation back of amendments has no bearing here. . . . The relation back doctrine has nothing to do with the curing of jurisdictional defects in an earlier pleading.” *Id.* at 94. The First Circuit specifically distinguished its earlier holding in *USM Corp. v. GKN Fasteners Ltd.*, 578 F.2d 21 (1st Cir. 1978), upon which defendant Roxane relies here. Holding that “the proffered analogy [to *USM*] is flawed,” the First Circuit found that the plaintiff’s amendment “did not resort to the relation back mechanism in order to resurrect jurisdiction that had already been found wanting . . .” *Connectu*, 522 F.3d at 94. The First Circuit then held the district court could properly exercise jurisdiction over plaintiff’s amended complaint.

Similarly, the government’s claims in this matter relate back to the relator’s original complaint irrespective of defendants’ public disclosure/original source arguments, and this Court’s jurisdiction over the breadth of those claims is not subject to question. This result is also consistent with the recent amendments to the FCA concerning the relation back of the government’s complaint-in-intervention to the original *qui tam* complaint. Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21(4)(b). In the FERA provision at issue, Congress clarified its intent *ab initio* that all the government’s pleadings relate back to the filing of relator’s complaint where the claims arise out of the same conduct, transactions or occurrences as relator’s complaint. *Id.* FERA adds a new subsection (c) to Section 3731. (False Claims Procedure) and provides:

If the Government elects to intervene and proceed with an action brought under 3730(b), the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

There is no exception to this provision for *qui tam* complaints that are later found to be barred by the public disclosure rule and no basis for this Court to establish any such exception.

II. Government Reports Regarding AWP's Do Not Constitute Public Disclosures Under the FCA

Defendants argue that under the FCA's "public disclosure bar," 31 U.S.C. § 3730(e)(4)(A), relator's action is barred because reports issued by the government qualify as public disclosures and relator is not an original source. The determination of whether a relator's complaint should be dismissed for lack of subject matter jurisdiction requires a three-step inquiry. The court must determine: (1) whether the allegations or transactions in the complaint have been publicly disclosed in a manner provided by the statute; (2) if so, whether the relator's suit is "based upon" those allegations or transactions; and (3) if the answer to both of those questions is yes, whether the relator falls within the "original source" exception to the jurisdictional bar.⁴ *United States ex rel. O'Keefe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 91 (D. Mass. 2001).

This Court has adopted the widely accepted framework for determining whether a public

⁴ The FCA provides that a relator who seeks to avoid the jurisdictional bar must show that he has "voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B).

disclosure of the allegations or transactions has occurred as set forth in *United States ex rel. Springfield Terminal Railway Co. v. Quinn*, 14 F.3d 645, 655 (D.C. Cir. 1994). *Actavis*, 2009 WL 3171798 at *3; *O’Keefe*, 131 F. Supp. 2d at 94. Under *Springfield Terminal*, “if $X + Y = Z$, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.” *Actavis*, 2009 WL 3171798 at *3 (quoting *Springfield Terminal*, 14 F.3d at 654). Thus, absent the public disclosure of an allegation of fraud, both of the critical elements – “a misrepresented state of facts *and* a true state of facts” – must be in the public domain. *Springfield Terminal*, 14 F.3d at 655. The presence of one or the other, but not both, cannot be expected to set government investigators on the trail of fraud. *Id.* at 656.

The *Springfield Terminal* court further observed that “[k]nowledge of the allegedly misrepresented state of affairs – which does not necessarily entail knowledge of the fact of misrepresentation – is *always* in the possession of the government.” *Id.* In other words, through the very act of claims being presented to it, the government almost always learns at least some of the misrepresented facts, and when a government report acknowledges the presentation of specific claims for payment, one of the essential elements of the fraud may be considered to be in the public domain. Nonetheless, it is only when facts underlying the true state of affairs – that the services in fact were not rendered, the amount billed was inflated, or there was a kickback that made the claim ineligible for payment – *also* are in the public domain, that both the $X + Y$ may be present and the jurisdictional bar will be triggered. *Id.*

As this Court recently ruled, under the *Springfield Terminal* test, it is clear that the

government reports cited by defendants do not constitute a public disclosure of the allegations or transactions because they do not contain the essential elements of the fraud (both X and Y), and certainly do not contain an allegation of fraud (Z). For example, both Dey and Roxane point to a 1996 report by the Office of Inspector General for the Department of Health and Human Services (“HHS-OIG”), entitled “Medicare Payments for Nebulizer Drugs,” OEI-03-94-00390 (Feb. 1996). In this report, the HHS-OIG compares Medicare and Medicaid reimbursement for three nebulizer drugs, one of which is albuterol, a generic drug cited in the government’s case against Dey. The report concludes that Medicare is reimbursing at a higher rate than Medicaid for the same drugs, and catalogs the savings that would result if Medicare reimbursed similar to 17 states. OEI-03-94-00390 at 6. The report notes that (1) 13 of the 17 state Medicaid programs discount AWP by an average of 9.6%, (2) two state Medicaid programs reimburse at AWP, and (3) the remaining two states use wholesale acquisition cost (“WAC”). *Id.* at 7. The report recommends that Medicare consider various options to reduce reimbursement, including discounting from AWP. *Id.* at 11. Nowhere does the report discuss whether manufacturers are deliberately reporting inflated AWPs for any of the drugs, whether manufacturers are marketing the spread, or in fact anything about manufacturers’ conduct at all.

Abbott similarly points to a 1992 OIG report entitled “Cost of Dialysis-Related Drugs” (A-01-91-00526) as a public disclosure of the allegations and prices concerning Abbott’s vancomycin products. As with the reports cited by Dey and Roxane, there is absolutely no mention of fraud or misconduct by manufacturers, and neither Abbott nor its particular vancomycin products are even listed. Instead, as is typical of OIG reports in this area, average prices are listed for a group of drugs, without any identification of the manufacturer.

Furthermore, the report focuses on reimbursement under the End-Stage Renal Disease program, which is not at issue in this case.

Similarly, other government reports merely observe that providers often can purchase certain drugs for less than AWP. For example, another report cited by Dey and Roxane focuses on the Veterans Administration's ability to purchase drugs for less than what Medicare is reimbursing for various drugs. "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs," HHS-OIG, OEI-03-97-00293 (Nov. 1998). At most, the reports reflect a concern about the government's use of published AWP's to set drug reimbursement. To the extent the government reports place anything in the public domain, it is, at most, some information about reporting practices but not even half of the story of the fraudulent conduct. The true state of affairs -- that defendants may have (1) reported AWP's for their drugs that were inflated for the purpose of creating artificially large spreads, and (2) reported AWP's that virtually *no one* paid -- unquestionably was not placed in the public domain by virtue of the government reports defendants cite.⁵ Accordingly, those government reports do not constitute a public disclosure of the allegations or transactions of the instant suit, and simply do not trigger the application of the jurisdictional bar here.

⁵ Notably, in prior AWP matters in this district, pharmaceutical manufacturers have offered all the same types of reports for a variety of purposes, and the courts have properly ascribed little to no weight to them. As Judge Stearns observed, "[t]he recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct." *In re Lupron Marketing and Sales Practices Litig.*, 295 F. Supp. 2d 148, 168 n.19 (D. Mass. 2003).

CONCLUSION

For the reasons set forth above and in the plaintiffs' defendant-specific summary judgment briefs, plaintiffs respectfully request that the Court deny defendants' motions for summary judgment and motions to dismiss.

Respectfully Submitted,

For the United States of America,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above UNITED STATES' COMMON MEMORANDUM OF LAW IN OPPOSITION TO THE DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT PERTAINING TO THE STATUTE OF LIMITATIONS AND DEFENDANTS' MOTIONS TO DISMISS to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Date: November 2, 2009

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